

Notice of Allowability

Application No.

10/502,255

Applicant(s)

ALVARO ET AL.

Examiner

Zachary C. Tucker

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6 September 2006.
2. ☒ The allowed claim(s) is/are 1-11,15,17-21,27-80.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>27Apr,6Sep06</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone conversation between the examiner and applicants' counsel, Ms. Lorie Ann Morgan on 7 September 2006.

IN THE CLAIMS -

In claim 1, the second-to-last line on page 2 of the correspondence from applicants filed 6 September 2006, the phrase "* represents a chiral center" has been deleted.

In claim 53, line two, the word - - opiod- - has been deleted replaced with "opioid"

end of amendments

NOTE CHANGE OF EXAMINER

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This application is now before Zachary C. Tucker instead of the examiner to whom it was assigned previously.

Response to Amendment

Applicants' correspondences submitted 13 February 2006, including amendments to the claims, and submitted 6 September 2006, including amendments to the claims have been filed. The correspondence filed 13 February 2006 was submitted in response to a non-final Office action mailed 1 November 2005, which was prepared by an examiner other than the undersigned.

The version of the claims as amended and represented in the 7 September 2006 correspondence replaces all prior versions of the claims. The changes therein were prompted by conversations between the undersigned and applicants' counsel, Ms. Lorie Ann Morgan, on the 25th and 29th of August and on the 6th of September.

As requested by applicants in the 6 September 2006 correspondence (hereinafter "present amendment"), claims 1, 10, 11, 17, 21, 27-31, 33-35, 38, 39, 41, 42, 48, 56, 58-60, 62, 64, 69 and 74 have been amended, claims 22-26 have been cancelled and new claims 78-80 have been added.

Election/Restrictions

On 3 October 2005, election to prosecute the invention of Group I, as was set forth in the Restriction Groups in the Office action mailed in this case previously on 1 November 2005.

In the Reply to the Office action of 1 November 2005, applicants' counsel, Ms. Lorie Ann Morgan counsel strenuously urge that the Requirement as set forth in the November 1 2005 Office action be withdrawn.

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Arguments put forth by applicants' counsel at pages 14 and 15 of the reply to the Office action of 1 November 2005, filed 13 February 2006 are persuasive as to the matter of the Requirement for Restriction of the instant claims. Specifically, because the instant case was filed under 35 U.S.C. 371, so Unity of Invention Rules under the Patent Cooperation Treaty are operative. Under such Unity of Invention Rules, since the product (the compounds according to formula (I) claim 1) are a contribution over the prior art, they represent a special technical feature and methods of using the product and methods of making the product are all considered under the PCT rules to be one in the same invention.

Thus, the Requirement for Restriction set forth in the 1 November 2005 non-final Office action is hereby WITHDRAWN.

Status of Claim Rejections - 35 USC § 112

In the previous Office action, mailed 1 November 2005, claims 26-30, 35, 36, 39 and 42 were rejected under the first paragraph of 35 U.S.C. 112, for failing to comply with the enablement requirement.

In view of the amendments to the instant claims filed 6 September 2006, prompted by conversations with the new examiner charged with the instant application's prosecution, the previously stated rejections under this statute are hereby withdrawn.

Allowable Subject Matter

Claims 1-11,15,17-21,27-80 are allowed.

Claims drawn to compounds according to the present invention were indicated as allowable in the previous Office action mailed 1 November 2005. The amendment filed 6 September 2006 deletes "solvates" and replaces the term with the much narrower (and exemplified) hydrates of the compounds.

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Treatment of depressive disorders, panic and phobic disorders, sleep disorders, emesis and anxiety disorders, by administering a compound according to the present invention (an NK-1 receptor antagonist) to the subject in need of treatment therefor is enabled by the disclosure in light of the state of the art in what is known by the physician of ordinary skill in treating such conditions.

Applicants' submission of an Information Disclosure Statement filed 6 September 2006 includes citations of several articles showing that compounds having NK-1 receptor antagonist activity have plausible application as therapies for such conditions. The Information Disclosure Statement filed 27 April 2006 has also been considered by the examiner. Signed and initialed forms PTO 1449 to that effect are submitted with this Notice of Allowability.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

All Post-Allowance Correspondence concerning this application must be mailed to:
Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Or you can fax them to the Office of Patent Publications at 703-872-9306, in order to expedite the handling of such correspondence as amendments under 37 CFR 1.312; information disclosure statements, and formal drawings. Sending Post-Allowance papers to Technology Center 1600 will only cause delays in matching papers with the case.

For information concerning status of correspondence sent after receipt of the Notice of Allowance, please contact the Correspondence Branch at (703) 305-8027. The Notice of Allowance also has an insert containing contact information on other items, including Issue Fees, receipt of formal drawings and the status of the application.

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A handwritten signature in black ink, appearing to be "Z. D. H.", followed by a horizontal line.